

**KENTUCKY PANDEMIC INFLUENZA PREPAREDNESS PLAN  
VACCINE DISTRIBUTION AND USE SUPPLEMENT V**

	<b>TABLE OF CONTENTS</b>	
		<b>PAGE</b>
	<b>SUMMARY OF PUBLIC HEALTH ROLES AND RESPONSIBILITIES FOR VACCINE DISTRIBUTION AND USE</b>	<b>1</b>
<b>I.</b>	<b>RATIONALE</b>	<b>2</b>
<b>II.</b>	<b>OVERVIEW</b>	<b>2</b>
<b>III.</b>	<b>GUIDELINES FOR THE INTERPANDEMIC AND PANDEMIC ALERT PERIODS</b>	<b>2</b>
	<b>A. Vaccination Against Seasonal Influenza Virus Strains</b>	<b>2</b>
	<b>B. Responsibility of the Department for Public Health</b>	<b>3</b>
	<b>C. Responsibility of the Local Health Departments</b>	<b>3</b>
		<b>4</b>
<b>IV.</b>	<b>PREPAREDNESS PLANNING FOR VACCINATION AGAINST A PANDEMIC INFLUENZA STRAIN</b>	<b>4</b>
	<b>A. Vaccination of Priority Groups</b>	<b>4</b>
	<b>B. Responsibility of the Department for Public Health</b>	<b>4</b>
	<b>C. Responsibility of the Local Health Departments</b>	<b>4</b>
<b>V.</b>	<b>VACCINE DISTRIBUTION</b>	<b>4</b>
	<b>A. Distribution to Local Health Departments</b>	<b>5</b>
	<b>B. Distribution to Private Providers</b>	<b>5</b>
	<b>C. Second Dose Vaccination</b>	<b>6</b>
	<b>D. Contingency Plan for IND Use</b>	<b>6</b>
	<b>E. Vaccine Monitoring and Data Collection</b>	<b>7</b>
	<b>F. Vaccine Effectiveness</b>	<b>7</b>
	<b>G. Vaccine Supply and Distribution</b>	<b>7</b>
	<b>H. Kentucky's Immunization Registry</b>	<b>7</b>
	<b>I. Vaccine Coverage</b>	<b>8</b>
	<b>J. Vaccine Safety</b>	<b>8</b>
<b>VI.</b>	<b>RECOMMENDATIONS FOR THE PANDEMIC PERIOD</b>	<b>9</b>
	<b>A. Before a Vaccine is Available</b>	<b>9</b>
	<b>B. When a Vaccine Becomes Available</b>	<b>10</b>
<b>VII.</b>	<b>APPENDICES</b>	
	<b>APPENDIX A: Recommendations for Prioritization of Pandemic Influenza Vaccine</b>	<b>11</b>

## **SUMMARY OF PUBLIC HEALTH ROLES AND RESPONSIBILITIES FOR VACCINE DISTRIBUTION AND USE**

### **Interpandemic and Pandemic Alert Periods**

#### **A. Department for Public Health/Local Health Departments**

- Work with healthcare partners and other stakeholders to develop state-based plans for vaccine effectiveness, safety, distribution and use.

### **Pandemic Period**

#### **A. After the first reports of pandemic influenza are confirmed and before a pandemic vaccine becomes available**

##### **1. Department for Public Health/Local Health Department will:**

- Work with healthcare partners and other stakeholders to distribute, deliver, and administer vaccines to designated groups if stockpiled influenza vaccine of the pandemic subtype is available,
- Mobilize healthcare partners, and prepare to activate state-based plans for distributing and administering vaccines.
- Keep the healthcare and public health workforce up-to-date on projected timelines for availability of vaccines against pandemic influenza.
- Review modifications, if any, to recommendations on vaccinating priority groups.
- Accelerate training in vaccination and vaccine monitoring for public health staff and for partners responsible for vaccinating priority groups.
- Work with other governmental agencies and non-governmental organizations to ensure effective public health communications.

#### **B. After a vaccine becomes available**

##### **1. Department for Public Health/Local Health Departments will:**

- Work with healthcare partners and other stakeholders to distribute, deliver, and administer pandemic vaccines to priority groups.
- Monitor vaccine supplies, distribution, and use.
- Monitor and investigate adverse events.
- Phase-in vaccination of the rest of the population after priority groups have been vaccinated.
- Provide updated information to the public via the news media.
- Work with federal partners to evaluate vaccine-related response activities when the pandemic is over.

## **I. RATIONALE**

The initial response to an influenza pandemic will include medical care, community containment and personal protective measures, and targeted use of antiviral drugs. Before a vaccine containing the circulating pandemic virus strain becomes available, pre-pandemic vaccine from stockpiles (if available for the pandemic subtype or partially cross-protective to the circulating virus) may be considered for persons in designated priority groups. Once a vaccine against the circulating pandemic virus strain becomes available, its distribution and delivery will be a major focus of pandemic response efforts to:

- Ensure efficient and equitable distribution of pandemic vaccine, according to priority lists.
- Rapidly determine vaccine effectiveness.
- Provide ongoing and timely monitoring of vaccine coverage.
- Provide ongoing and timely monitoring of vaccine safety.

## **II. OVERVIEW**

The Vaccine Supplement provides recommendations to state and local partners and other stakeholders on planning for the different elements of a pandemic vaccination program. The recommendations for the Interpandemic and Pandemic Alert Periods focus on planning for vaccine distribution, vaccination of priority groups, monitoring of adverse events, tracking of vaccine supply and administration, vaccine coverage and effectiveness studies, communications, legal preparedness, and training. The recommendations for the Pandemic Period focus on working with healthcare partners to implement plans for vaccination against pandemic influenza and initiate monitoring activities.

Additional issues that might be of interest to healthcare partners that administer vaccine are addressed in the Healthcare Planning Supplement.

## **III. GUIDELINES FOR THE INTERPANDEMIC AND PANDEMIC ALERT PERIODS**

### **A. Vaccination Against Seasonal Influenza Virus Strains**

During the Interpandemic Period, the Department for Public Health in coordination with local health departments will work with healthcare partners to:

1. Enhance levels of seasonal influenza vaccination in groups at risk for severe influenza and in healthcare workers.
  - The success of the pandemic influenza vaccination program will be determined in large part by the strength of state and local vaccination programs during the Interpandemic Period. Higher annual vaccination rates will foster increased familiarity with and public confidence in influenza vaccines, increased manufacturing capacity for influenza vaccines, and strengthened distribution channels.

2. Enhance levels of pneumococcal polysaccharide vaccination for whom it is recommended.
  - Increased use of pneumococcal polysaccharide vaccine may decrease rates of secondary bacterial infections during a pandemic. Because large-scale pneumococcal vaccination might not be feasible once a pandemic occurs, the Interpandemic Period and Pandemic Alert is the ideal time to deliver this preventive measure. Pneumococcal vaccine is indicated for most persons for whom influenza vaccine is recommended.

## **B. Responsibility of the Department for Public Health**

- Provide guidance to local health departments during seasonal epidemics of influenza regarding vaccine procurement, effectiveness, safety, distribution and use.
- Use the Health Alert Network during seasonal epidemics of influenza to provide an open line of communication to local health departments in regard to state-wide vaccine supply.
- Provide guidance to the general population during seasonal epidemics of influenza regarding vaccine effectiveness and availability using the Cabinet for Health and Family Services' influenza Web address ([www.chfs.ky.gov/KDPH/Influenza.htm](http://www.chfs.ky.gov/KDPH/Influenza.htm)) and an influenza telephone hotline (502-564-5353).
- Conduct frequent meetings of the Seasonal Influenza Committee within the Department for Public Health to monitor state-wide vaccine distribution, administration and potential shortages.
- Communicate vaccine prioritization to local health departments, private providers and the general public in the event of a vaccine shortage.
- Work with stakeholders (Schools of Public Health, long term care facilities, private providers, employer groups and other health related organizations) to strengthen influenza and pneumococcal vaccination efforts.

## **C. Responsibility of the Local Health Departments**

- Conduct county-wide assessments for seasonal epidemics of influenza regarding vaccine procurement by long term care facilities, hospitals and private physicians to determine anticipated vaccine supply.
- Provide vaccine inventory and administration data to the Department for Public Health utilizing the Health Alert Network.
- Provide information and education to the population regarding vaccine effectiveness, vaccine supply and prioritization of vaccine.
- Emphasize the importance of late season vaccination and fully utilize vaccine supply.
- Provide pneumococcal vaccination to eligible individuals.
- Exercise mass vaccination plans in preparation for a potential pandemic.
- Develop a partnership with other community healthcare providers in regard to influenza vaccination.

#### **IV. PREPAREDNESS PLANNING FOR VACCINATION AGAINST A PANDEMIC INFLUENZA STRAIN**

##### **A. Vaccination of Priority Groups**

During a pandemic, changes may be made based on the characteristics of the causative virus (e.g., transmissibility, virulence, initial geographic distribution, age-specific attack rates, and complication rates) and on vaccine effectiveness. The Department for Public Health will comply with the National Vaccine Advisory Committee (NVAC) and Advisory Committee on Immunization Practices (ACIP) Recommendations for Prioritization of Pandemic Influenza Vaccine as they apply to Kentucky residents. Any changes in the NVAC/ACIP recommendations will be reflected in the Kentucky Recommendations for Prioritization of Pandemic Influenza Vaccine (Appendix 1) issued in the Kentucky Pandemic Influenza Preparedness and Response Plan.

##### **B. The following activities will be the Responsibility of the Department for Public Health:**

- In collaboration with Regional Epidemiologists, Public Health Preparedness Planners and Local Health Departments, KDPH will enumerate essential priority groups at the state level.
- Provide guidance to local health departments and other healthcare providers on any changes made to priority groups due to the epidemiology of the novel virus.
- Educate professional organizations and other stakeholders about the need for priority groups and the rationale for the groups currently recommended.

##### **C. The following activities will be the responsibility of the Local Health Departments:**

- Identify and enumerate recommended priority groups at the local level.
- Develop a plan on how persons in priority groups would be identified at vaccination clinics and how vaccine would most efficiently be provided to those groups.
- Provide education on priority groups and rationale to healthcare providers and residents in the community.

#### **V. VACCINE DISTRIBUTION**

HHS is working to expand pandemic influenza vaccine production capacity and will signal to manufacturers when to shift from annual to pandemic vaccine production and assure that pandemic vaccine is produced at full capacity.

At the onset of an influenza pandemic, HHS, in concert with U.S. Congress in collaboration with the states, will work with the pharmaceutical industry to acquire vaccine directed against the pandemic strain. Distribution of pandemic vaccine to health departments and providers will occur via private-sector vaccine distributors or directly via manufacturer. Only stockpiled pre-pandemic vaccine would be distributed by the

federal government, if used. Due to the uncertainty of the method of distribution, multiple methods of distribution are accounted for in this plan.

#### **A. Distribution to Local Health Departments**

If vaccine is delivered to the Department for Public Health in coordination with the federal government or directly from vaccine manufacturers, the following distribution plan will be activated:

- Receipt of vaccine by the state and distribution to local health departments/districts will follow the guidelines set forth in Kentucky Emergency Operations Plan Appendix M-10 (Strategic National Stockpile Program).
- If vaccine is delivered to local health departments/districts directly from vaccine manufacturers, the following activities will be the responsibility of the local health departments/districts:
  - Local health departments/districts will provide vaccination to persons in priority groups.
  - Local health departments/districts will activate established and exercised plans for mass vaccination while ensuring efficient and equitable distribution of pandemic vaccine, according to priority lists.
  - Maintain strategies and equipment to ensure vaccine security issues, cold chain requirements, and transport and storage issues.
  - Identify locations for vaccination clinics that will be operated by health departments and enter into memoranda of agreement with organizations that agree to provide vaccinators or other staff.
  - Develop procedures for collecting, removing, and disposing of used syringes, needles, and other vaccination supplies
  - Develop a plan for training vaccinators and other staff responsible for mass vaccination.
  - Develop strategies for vaccinating hard-to-reach populations
- Local health departments/districts plans should also specifically address the delivery of pandemic vaccine to medically underserved and migrant populations to improve equity in access within priority groups and, later, the general population.

#### **B. Distribution to Private Providers**

If vaccine is administered by private-sector organizations or providers at offices, clinics, or other sites, KDPH will be responsible for the following:

- Providing vaccination information to healthcare providers regarding priority groups, vaccine safety and effectiveness, storage and handling, etc.
- Utilize Immunization Program field staff to collect and redistribute unused vaccine from healthcare providers who have met their priority vaccination goals.
- Monitoring vaccine administration so that it follows existing plans on priority groups based on data submitted by local health departments/districts.

Local health departments/districts will be responsible for the following:

- Providing vaccination information to healthcare providers regarding priority groups, vaccine safety and effectiveness, storage and handling, etc.
- Collecting data from vaccinating providers on inventory, vaccine administration, priority group eligibility screening, etc.
- Reporting collected information to the KDPH via the Health Alert Network, utilizing the format described in the “Vaccine Monitoring and Data Collection” portion of this supplement.

### **C. Second Dose Vaccinations**

A vaccine against pandemic influenza will likely require two doses, administered at least a month apart, to provide a level of immunity comparable to that obtained with seasonal influenza vaccines. Recommendations on the number of required doses and the timing of the second dose will be issued once immunogenicity trials have been completed.

If two doses are required to achieve immunity, it will be necessary to ensure that vaccinated persons return for the second dose. KDPH along with local health departments/districts will be responsible for the following:

- Arrange for information about the need for a second dose to be provided at the time of vaccination.
- Ensure that planning for vaccine procurement and distribution to clinics and other facilities accounts for the need to use portions of future shipments for second doses, thus reducing the number of available first doses.
- Use immunization registry or another system that would accomplish the goals of pandemic vaccination.

### **D. Contingency Plan for Investigational New Drug (IND) Use**

State and local health departments should be prepared to distribute unlicensed vaccines (if needed) under FDA’s IND provisions. Unlicensed vaccines might be needed, for example, if pandemic spread is rapid and standard vaccine efficacy and safety tests are not completed before the response.

IND provisions require strict inventory control and record-keeping, completion of a signed consent form from each vaccine recipient, and mandatory reporting of specified types of adverse events. IND provisions also require approval from Institutional Review Boards (IRBs) in hospitals, health departments, and other vaccine-distribution venues. The FDA regulations permit the use of a national or "central" IRB. A treatment IND is one IND mechanism that FDA has available for use and is especially suited for large scale use of investigational products.

As an alternative to IND use of an unapproved antiviral drug, HHS may utilize the drug product under Emergency Use Authorization procedures as described in the FDA draft Guidance "Emergency Use Authorization of Medical Products".

#### **E. Vaccine Monitoring and Data Collection**

To ensure optimal use of a new pandemic influenza vaccine, state and local health departments should be prepared to collect data on vaccine effectiveness, vaccine supply and distribution, vaccine coverage, and vaccine safety.

#### **F. Vaccine Effectiveness**

Vaccine effectiveness will be assessed by comparing rates of influenza-related illness, hospitalization, and/or death among vaccinated and unvaccinated persons. These studies will be implemented by CDC in collaboration with healthcare and university partners and with state and local health departments that participate in influenza surveillance systems.

#### **G. Vaccine Supply and Distribution**

Mechanisms for tracking vaccine supply and distribution will depend on how vaccine is purchased and distributed. Tracking will be implemented by state and local health authorities who will have the major responsibility for allocation decisions and will be working in association with CDC and vaccine producers. Data also will be obtained from vaccine producers and commercial distributors.

- Vaccine tracking and coverage information may be used by federal, state, and local decision makers to estimate adverse event rates based on the number of doses administered and to determine if vaccine is being administered according to established priority groups for pandemic vaccine (especially in the early phases of vaccination). Data will be collected from individual providers, collated at the local and state levels, and reported to federal authorities on a scheduled routine basis.
- The Kentucky Immunization Registry may be adapted to track coverage with pandemic influenza vaccine. Kentucky may also use a vaccine database that will be supplied by CDC. At a minimum, tracking data should include:
  - Number of doses administered, by date and age, priority group, and state or county (or zip code)
  - Number of doses that represent second doses, as applicable

Currently, the Department for Public Health utilizes the Health Alert Network to collect inventory and administration data for seasonal influenza and barring further instruction from CDC, would continue to utilize that method in a pandemic.

#### **H. Kentucky's Immunization Registry**

Kentucky's Immunization Registry is being developed by the Department for Public Health and should be operational in 2007. The Immunization Registry will be a confidential, population-based, computerized system for maintaining information



regarding vaccinations. The Registry will include persons in the geographic area of the Commonwealth of Kentucky and will provide a single data source for all community vaccination partners, offering benefits to parents, communities, and health-care providers. The Registry will electronically store data on all core data elements that are recommended and approved by the NVAC. A Registry record will be created within 6 weeks of birth for each newborn child in Kentucky. The Registry will enable access to and retrieval of vaccination information at the time of encounter and will produce official immunization certificates; Encounter information will be received and processed within 1 month of vaccine administration. The Registry will automatically determine the routine childhood vaccination(s) needed, in compliance with current ACIP recommendations when an individual presents for a scheduled vaccination. Individuals will be automatically identified when due or late for vaccination(s) to enable the production of reminder/recall notifications. Immunization coverage reports will be automatically produced and stratified by providers, age groups, and geographic area. Electronic data will be exchanged with external systems using Health Level 7 standards. State-of-the-art technology will protect the confidentiality of stored healthcare data and will ensure the confidentiality and security of healthcare information contained.

The Immunization Registry will be architecturally connected to and functionally interoperable with the Kentucky Electronic Disease Surveillance System (KY-EDSS), which is the Commonwealth's implementation of the federal initiative called the National Electronic Disease Surveillance System (NEDSS). This system is designed to detect infectious disease outbreaks rapidly, to facilitate the electronic transfer of appropriate clinical information from external systems to the Department for Public Health, to reduce the provider burden in the provision of information, and to enhance both the timeliness and quality of information provided. The Immunization Registry provides application software functionality for the KY-EDSS to monitor and report information about vaccine preventable diseases. In turn, the NEDSS Logical Data Model includes many database tables and relationships that are used to support immunization efforts.

Effective use of the Immunization Registry during an infectious disease emergency requires a high emphasis on electronically maintaining associated demographic (home and occupation), contact (communicable disease tracing), clinical, geospatial and event (threat, facility, etc.) data in forms that can be readily associated, re-linked and processed. Automated record linking capabilities are specifically designed to facilitate data exchange between partners. During an infectious disease emergency, public health agencies will be able to use Immunization Registry components to manage case contacts given prophylaxis, help identify populations at high risk and persons who are under-vaccinated, monitor the progress of prophylaxis, produce summary reports on outcomes, and support provider and consumer education.

## **I. Vaccine Coverage**

CDC will work with states to develop a system for monitoring vaccination rates at regular intervals, using a pre-existing population-based survey tool (e.g., Behavioral Risk Factor

Surveillance System) that provides national and state-level estimates and complements the vaccine tracking systems described above.

## **J. Vaccine Safety**

In response to vaccine safety, the Kentucky Immunization Program will use a system to report and investigate adverse events following immunization (AEFI) with a pandemic influenza vaccine. The following activities will be the responsibility of the Department for Public Health:

- Any person in the state of Kentucky (private citizen, private provider or health department) may fill out and send a Vaccine Adverse Event and Reporting System (VAERS) form to the Department for Public Health.
- VAERS forms are available at local health departments or by contacting the Immunization Program at the Department for Public Health.
- The Immunization Program VAERS Coordinator, who serves as the state's contact with federal government staff overseeing VAERS, will collect the VAERS form, review for completion and assign a specific Kentucky number for each report.
- The specific Kentucky (KY) number can have identifiers attached to track specific cases.
- After a KY number is assigned, the VAERS form will then be submitted to the VAERS central office via the Internet, by fax, or by mail.
- The hard copy of the VAERS form is kept on file for future follow-up.

Adverse events related to use of IND vaccines may be reported through other mechanisms in addition to or in place of VAERS, in accordance with specific regulatory or policy requirements. Adverse events will also be monitored through the Vaccine Safety Datalink (<http://www.cdc.gov/nip/vacsafe/default.htm#VSD>), a network of seven geographically diverse health maintenance organizations through which active surveillance vaccine safety studies are conducted. Another potential resource for vaccine safety research is CDC's Clinical Immunization Safety Assessment (CISA) network (<http://www.vaccinesafety.org/CISA/index.htm>).

## **VI. RECOMMENDATIONS FOR THE PANDEMIC PERIOD**

### **A. Before a Vaccine is Available**

Before a vaccine becomes available, state and local health departments should:

- Meet with partners and stakeholders to review the major elements of the state's vaccine distribution plan.
- Modify the plan to account for possible updated interim recommendations on priority groups, projected vaccine supplies and timelines for availability, and staffing estimates for mass vaccination.

- Notify the medical community about the status of the plan and the expected availability of vaccines.
- Work with healthcare partners and other stakeholders to distribute, deliver, and administer vaccines to designated groups if stockpiled vaccine of the pandemic subtype is available.
- Update and disseminate public information on the production, distribution, and use of pandemic influenza vaccine before it becomes available.
- Conduct training for public health staff and partners involved in distributing and administering vaccines.

## **B. When a Vaccine Becomes Available**

- Once a vaccine is ready for distribution, state and local health departments should work with healthcare and community partners to activate plans to:
  - Vaccinate persons in priority groups, in accordance with existing recommendations.
  - Provide a second dose, if required for immunity.
  - Monitor vaccine supply, distribution, and use.
  - Monitor and investigate adverse events.
  - Continue communication with partners and the public.
- After priority groups have been vaccinated and additional vaccine stocks become available, public health authorities should phase-in vaccination for the remainder of the population, based on age or other criteria that will ensure fair, equitable, and orderly distribution. HHS will issue national recommendations to aid in this process.
- After the pandemic has ended, state and local health departments should evaluate all response activities, including vaccine tracking and delivery, adverse event monitoring, and communications.

## APPENDIX A

### Recommendations for Prioritization of Pandemic Influenza Vaccine

The following recommendations are reflective of the prioritization recommendations set forth by the Advisory Committee on Immunization Practices (ACIP) and the National Vaccine Advisory Committee (NVAC) in the Department for Health and Human Services (HHS) Pandemic Influenza Plan. Although the advisory committees considered potential priority groups broadly, the main expertise of the members was in health and public health. The primary goal of a pandemic response was to decrease health impacts including severe morbidity and death. A secondary pandemic response goal was to minimize societal and economic impacts. However, as other sectors are increasingly engaged in pandemic planning, additional considerations may arise. The advisory committee reports explicitly acknowledge the importance of this, for example highlighting the priority for protecting critical components of the military. Finally, HHS has recently initiated outreach to engage the public and obtain a broader perspective into decisions on priority groups for pandemic vaccine and antiviral drugs. Though findings of the outreach are preliminary, a theme that has emerged is the importance of limiting the effects of a pandemic on society by preserving essential societal functions.

The Kentucky Department for Public Health (KDPH) recommendations for prioritization will continue to reflect the recommendations set forth by the Centers for Disease Control and Prevention (CDC) and the HHS. We recognize the potential for alterations of these recommendations in the case of a pandemic depending upon the epidemiology of a novel strain and will reiterate the need to refer to national recommendations for changes that may occur.

The Constitution of the Commonwealth of Kentucky affords the Governor of Kentucky, or his designee, the discretionary ability to restructure the prioritization during an influenza pandemic. In addition, the recommendations for prioritization of vaccination may be further modified at a local level by the chief elected official.

#### A. Critical Assumptions

The recommendations were based on the following critical assumptions:

- **Morbidity and mortality.** The greatest risk of hospitalization and death—as during the 1957 and 1968 pandemics and annual influenza—will be in infants, the elderly, and those with underlying health conditions. In contrast, during the 1918 pandemic, most deaths occurred in young adults, highlighting the need to reconsider the recommendations at the time of the pandemic based on the epidemiology of disease.
- **Healthcare system.** The healthcare system will be severely taxed if not overwhelmed due to the large number of illnesses and complications from influenza requiring hospitalization and critical care. CDC models estimate increases in hospitalization and intensive care unit demand of more than 25% even in a moderate pandemic.

- **Workforce.** During a pandemic wave in a community, between 25% and 30% of persons will become ill during a 6 to 8 week outbreak. Among working-aged adults, illness attack rates will be lower than in the community as a whole. A CDC model suggests that at the peak of pandemic disease, about 10% of the workforce will be absent due to illness or caring for an ill family member. Impacts will likely vary between communities and work sites and may be greater if significant absenteeism occurs because persons stay home due to fear of becoming infected.
- **Critical infrastructure.** Only limited information was available from which to assess potential impacts on critical infrastructure sectors such as transportation and utility services. Because of changes in business practices and the complexity of networks, information from prior pandemics was not considered applicable.
- **Vaccine production capacity.** The U.S.-based vaccine production capacity was assumed at 3 to 5 million doses (15 mcg) per week with 3 to 6 months needed before the first doses are produced. Two doses per person were assumed to be required for protection. Subsequent results of a National Institute of Health (NIH) clinical trial of influenza A (H5N1) vaccine suggest that higher doses of antigen will be needed to elicit a good immune response; thus, the assumptions made by the committee could potentially substantially exceed the amount of vaccine that would be produced.

#### Vaccine Priority Group Recommendations\*

Tier	Subtier	Population	Rationale
1	A	<ul style="list-style-type: none"> <li>• Medical workers and public health workers who are involved in direct patient contact, other support services essential for direct patient care, and vaccinators</li> </ul>	<ul style="list-style-type: none"> <li>• Healthcare workers are required for quality medical care (studies show outcome is associated with staff-to-patient ratios). There is little surge capacity among healthcare sector personnel to meet increased demand</li> </ul>
1	B	<ul style="list-style-type: none"> <li>• Persons &gt; 65 years with 1 or more influenza high-risk conditions, not including essential hypertension</li> <li>• Persons 6 months to 64 years with 2 or more influenza high-risk conditions, not including essential hypertension</li> <li>• Persons 6 months or older with history of hospitalization for pneumonia or influenza or other influenza high-risk condition in the past year</li> </ul>	<ul style="list-style-type: none"> <li>• These groups are at high risk of hospitalization and death. Excludes elderly in nursing homes and those who are immunocompromised and would not likely be protected by vaccination</li> </ul>

1	C	<ul style="list-style-type: none"> <li>• Pregnant women</li> <li>• Household contacts of severely immunocompromised persons who would not be vaccinated due to likely poor response to vaccine</li> <li>• Household contacts of children &lt;6 month olds</li> </ul>	<ul style="list-style-type: none"> <li>• In past pandemics and for annual influenza, pregnant women have been at high risk; vaccination will also protect the infant who cannot receive vaccine.</li> <li>• Vaccination of household contacts of immunocompromised and young infants will decrease risk of exposure and infection among those who cannot be directly protected by vaccination</li> </ul>
1	D	<ul style="list-style-type: none"> <li>• Public health emergency response workers critical to pandemic response</li> <li>• Key government leaders</li> </ul>	<ul style="list-style-type: none"> <li>• Critical to implement pandemic response such as providing vaccinations and managing/monitoring response activities</li> <li>• Preserving decision-making capacity also critical for managing and implementing a response</li> </ul>

Tier	Subtier	Population	Rationale
2	A	<ul style="list-style-type: none"> <li>• Healthy 65 years and older</li> <li>• 6 months to 64 years with 1 high-risk condition</li> <li>• 6-23 months old, healthy</li> </ul>	<ul style="list-style-type: none"> <li>• Groups that are also at increased risk but not as high risk as population in Tier 1B</li> </ul>
2	B	<ul style="list-style-type: none"> <li>• Other public health emergency responders</li> <li>• Public safety workers including police, fire, 911 dispatchers, and correctional facility staff</li> <li>• Utility workers essential for maintenance of power, water, and sewage system functioning</li> <li>• Transportation workers transporting fuel, water, food, and medical supplies as well as public ground public transportation</li> <li>• Telecommunications/IT</li> </ul>	<ul style="list-style-type: none"> <li>• Includes critical infrastructure groups that have impact on maintaining health (e.g., public safety or transportation of medical supplies and food); implementing a pandemic response; and on maintaining societal functions</li> </ul>

		for essential network operations and maintenance	
3		<ul style="list-style-type: none"> <li>• Other key government health decision-makers</li> <li>• Funeral directors/embalmers</li> </ul>	<ul style="list-style-type: none"> <li>• Other important societal groups for a pandemic response but of lower priority</li> </ul>
4		<ul style="list-style-type: none"> <li>• Healthy persons 2-64 years not included in above categories</li> </ul>	<ul style="list-style-type: none"> <li>• All persons not included in other groups based on objective to vaccinate all those who want protection</li> </ul>

\*The committee focused its deliberations on the U.S. civilian population. ACIP and NVAC recognize that Department of Defense (DOD) needs should be highly prioritized. DoD Health Affairs indicates that 1.5 million service members would require immunization to continue current combat operations and preserve critical components of the military medical system. Should the military be called upon to support civil authorities domestically, immunization of a greater proportion of the total force will become necessary. These factors should be considered in the designation of a proportion of the initial vaccine supply for the military.

Other groups also were not explicitly considered in these deliberations on prioritization. These include American citizens living overseas, non-citizens in the U.S., and other groups providing national security services such as the border patrol and customs service.

## **B. Definitions and rationales for priority groups**

### **1. Healthcare workers and essential healthcare support staff**

a) Definition  
Healthcare workers (HCW) with direct patient contact (including acute-care hospitals, nursing homes, skilled nursing facilities, urgent care centers, physician's offices, clinics, home care, blood collection centers, and EMS) and a proportion of persons working in essential healthcare support services needed to maintain healthcare services (e.g. dietary, housekeeping, admissions, blood collection center staff, etc.). Also included are healthcare workers in public health with direct patient contact, including those who may administer vaccine or distribute influenza antiviral medications, and essential public health support staff for these workers.

b) Rationale  
The pandemic is expected to have substantial impact on the healthcare system with large increases in demand for healthcare services placed on top of existing demand. HCW will be treating influenza-infected patients and will be at risk of repeated exposures. Further, surge capacity in this sector is low. To encourage continued work in a high-exposure setting and to help lessen the risk of healthcare workers transmitting influenza to other patients and HCW family members, this group was highly prioritized. In addition, increases in bed/nurse ratios have been associated with increases in overall patient mortality. Thus, substantial absenteeism may affect overall patient care and outcomes.

## 2. Groups at high risk of influenza complications

a) Definition  
Persons 2-64 years with a medical condition for which influenza vaccine is recommended and all persons 6-23 months and 65 years and older. Excludes nursing home residents and severely immunocompromised persons who would not be expected to respond well to vaccination.

b) Rationale  
These groups were prioritized based on their risk of influenza-related hospitalization and death and also their likelihood of vaccine response. Information from prior pandemics was used whenever possible, but information from interpandemic years was also considered. Nursing home residents and severely immunocompromised persons would be prioritized for antiviral treatment and/or prophylaxis and vaccination of healthcare workers and household contacts who are most likely to transmit influenza to these high risk groups.

## 3. Critical infrastructure

a) Definitions and rationale  
Those critical infrastructure sectors that fulfill one or more of the following criteria:

- Have increased demand placed on them during a pandemic
- Directly support reduction in deaths and hospitalization;
- Support the healthcare sector and other emergency services
- Supply basic necessities and services critical to support of life and healthcare or emergency services.

Groups included in critical infrastructure are needed to respond to a pandemic and to minimize morbidity and mortality, and include the following sectors:

- Key government leaders and health decision-makers who will be needed to quickly move policy forward on pandemic prevention and control efforts
- Public safety workers (firefighters, police, and correctional facility staff, including dispatchers) are critical to maintaining social functioning and order and will contribute to a pandemic response, for example by ensuring order at vaccination clinics and responding to medical emergencies
- Utility service workers (water, power, and sewage management) are prioritized as the services they provide are also essential to the healthcare system as well as to preventing additional illnesses from lack of these services unrelated to a pandemic.
- Transportation workers who maintain critical supplies of food, water, fuel, and medical equipment and who provide public transportation, which is essential for provision of medical care and transportation of healthcare workers to work and transportation of ill persons for care
- Telecommunication and information technology services critical for maintenance and repairs of these systems are also essential as these systems are now critical for accessing and delivering medical care and in support of all other critical infrastructure
- Mortuary services will be substantially impacted due to the increased numbers of deaths from a pandemic and the fact that impact will be high in the elderly, a growing segment of the population



#### **4. Public health emergency response workers**

a) Definition  
This group includes persons who do not have direct patient care duties, but who are essential for surveillance for influenza, assessment of the pandemic impact, allocation of public health resources for the pandemic response, development and implementation of public health policy as part of the response, and development of guidance as the pandemic progresses.

b) Rationale  
Persons in this sector have been critical for past influenza vaccine pandemics and influenza vaccine shortages and little surge capacity may be available during a public health emergency such as a pandemic.

#### **5. Persons in skilled nursing facilities**

a) Definition  
Patients residing in skilled nursing facilities. Not included in this group are persons in other residential settings (e.g., assisted living) who are more likely to be mobile, in a setting that is less closed, and have decentralized healthcare.

b) Rationale  
This group was not prioritized for vaccine because of the medical literature finding of poor response to vaccination and occurrence of outbreaks even in the setting of high vaccination rates. Other studies have suggested that vaccination of healthcare workers may be a more effective strategy to prevent influenza in this group. Further, surveillance for influenza can be conducted in this group and antiviral medications used widely for prophylaxis and treatment. Ill visitors and staff should also be restricted from visiting nursing home facilities during outbreaks of pandemic influenza. This strategy for pandemic influenza vaccine differs from the interpandemic vaccination strategy of aggressively vaccinating nursing home residents. The rationale considers several factors: 1) these populations are less likely to benefit from vaccine than other groups who are also at high risk; 2) other prevention strategies feasible for this group are not possible among other high-risk groups; 3) the overall morbidity and mortality from pandemic is likely to severely impact other groups of persons who would be expected to have a better response to the vaccine; and 4) a more severe shortage of vaccine is anticipated.

#### **6. Severely immunocompromised persons**

a) Definition  
Persons who are undergoing or who have recently undergone bone marrow transplantation and others with severe immunodeficiency (e.g., AIDS patients with CD4 counts <50, children with SCID syndrome, recent bone marrow transplant patients). The numbers of persons in these categories is likely much smaller than the anticipated number assumed in tiering above, but sources for more specific estimates have not been identified.

b) Rationale  
These groups have a lower likelihood of responding to influenza vaccination. Thus, strategies to prevent severe influenza illness in this group should include vaccination of healthcare workers and household contacts of severely immunocompromised persons and

use of antiviral medications. Consideration should be given to prophylaxis of severely immunocompromised persons with influenza antivirals and early antiviral treatment should they become infected.

## **7. Children <6 months of age**

a)

Rationale

Influenza vaccine is poorly immunogenic in children <6 months and the vaccine is currently not recommended for this group. In addition, influenza antiviral medications are not FDA-approved for use in children <1 year old. Thus, vaccination of household contacts and out-of-home caregivers of children <6 months is recommended to protect this high-risk group. Influenza vaccine administered to pregnant women may provide some protection to children for several months after their birth.

## **C. Other discussion**

There was substantial discussion on priority for children. Four potential reasons were raised for making vaccination of children a priority:

1. At the public engagement session, many participants felt that children should have high priority for vaccination.
2. Children play a major role in transmitting infection, and vaccinating this group could slow the spread of disease and indirectly protect others.
3. Children have strong immune systems and will respond well to vaccine whereas vaccination of the elderly and those with illnesses may be less effective.
4. Some ethical frameworks would support a pediatric priority.

ACIP and NVAC did not make children a priority (other than those included in tiers, because of their underlying diseases [Tiers 1B and 2A] or as contacts of high-risk persons [Tier 1C]) for several reasons:

- Healthy children have been at low risk for hospitalization and death in prior pandemics and during annual influenza seasons.
- It is uncertain whether vaccination of children will decrease transmission and indirectly protect others. Studies that show this impact or mathematical models that predict it rely on high vaccination coverage that may not be possible to achieve given limited supplies in a pandemic.
- The committees recognize that this is an area for further scientific work; that children may be a good target population for live-attenuated influenza vaccine (FluMist®) if it is available; and that education of the public will be needed to provide the rationale for the recommendations.